IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

TONI MARIE WATKINS,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-20370

COOK INCORPORATED, et al.,

Defendants.

MEMORANDUM OPINION & ORDER
(*Daubert* Motions)

Pending before the court are the following motions brought by the defendants: (1) Motion to Exclude the Opinions and Testimony of Donald Kreutzer, Ph.D. [Docket 36]; (2) Motion to Exclude the Opinions and Testimony of Lisa Morici, Ph.D. [Docket 38]; and (3) Motion to Exclude the Opinions and Testimony of Daniel S. Elliott, M.D. [Docket 40].

Also pending before the court are the following motions brought by the plaintiff: (1) Motion to Exclude General Liability/Causation Testimony of Anthony Atala, M.D. [Docket 30]; (2) Motion to Exclude General Liability/Causation Testimony of Mickey Karram, M.D. [Docket 31]; (3) Motion to Exclude General Liability/Causation Testimony of Dennis Metzger, Ph.D. [Docket 32]; (4) Motion to Exclude the Testimony of Dr. Stephen Park Rhodes [Docket 33]; (5) Motion to Exclude Expert Testimony of Improperly Designated Employees [Docket 34]; and (6) Motion to Exclude General Liability/Causation Testimony of Robert L. Long, M.D. [Docket 35].

For the reasons discussed below, defendants' Motion to Exclude the Opinions and Testimony of Donald Kreutzer, Ph.D. [Docket 36] is **DENIED**; defendants' Motion to Exclude the Opinions and Testimony of Lisa Morici, Ph.D. [Docket 38] is **GRANTED in part** and

DENIED in part; defendants' Motion to Exclude the Opinions and Testimony of Daniel S. Elliott, M.D. [Docket 40] is **DENIED**; plaintiff's Motion to Exclude General Liability/Causation Testimony of Anthony Atala, M.D. [Docket 30] is **DENIED**; plaintiff's Motion to Exclude General Liability/Causation Testimony of Dennis Metzger, Ph.D. [Docket 32] is **DENIED**; plaintiff's Motion to Exclude the Testimony of Dr. Stephen Park Rhodes [Docket 33] is **GRANTED**; and plaintiff's Motion to Exclude Expert Testimony of Improperly Designated Employees [Docket 34] is **DENIED**. It is further **ORDERED** that Cook provide the plaintiff with expert compensation information for Dr. Atala and updated disclosures for its corporate experts within **seven days** of the entry of this Memorandum Opinion and Order. Finally, the court **RESERVES** judgment on plaintiff's Motion to Exclude General Liability/Causation Testimony of Mickey Karram, M.D. [Docket 31] and plaintiff's Motion to Exclude General Liability/Causation Testimony of Robert L. Long, M.D. [Docket 35].

I. Background

This case against Cook Incorporated, Cook Biotech, Inc., and Cook Medical, Inc. (collectively "Cook") resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI").[1] In the seven MDLs, there are more than 70,000 cases currently pending, approximately 350 of which are in the Cook MDL, MDL 2440. In this particular case, the plaintiff, Toni Maria Watkins, was surgically implanted with the Stratasis Urethral Sling ("Stratasis"), a pelvic repair product made of SIS material that Cook manufactures to treat SUI. (Compl. [Docket 1] ¶ 24). Ms. Watkins received her surgery at Floyd

[1] In the interest of clarity, I note that the pelvic repair products manufactured by Cook do not contain polypropylene mesh like most of the products at issue in the other MDLs before this court. Rather, Cook manufactures its products using a biologic material made from porcine small intestinal submucosa ("SIS"), (Compl. [Docket 1] ¶ 5), which, in layman's terms, is the tissue from the small intestine of a pig.

Medical Center in Rome, Georgia, on April 5, 2004. (*Id.*). She now claims that as a result of the implantation of the Stratasis, she has "suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life." (*Id.* ¶ 1). Ms. Watkins advances the following causes of action against Cook: failure to warn under the Product Liability Act, strict liability, negligence, negligent misrepresentation, negligent infliction of emotional distress, breach of express warranty, breach of implied warranty, violation of consumer protection laws, gross negligence, unjust enrichment, and punitive damages. (*Id.* ¶¶ 41–130). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper.[2] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see*

[2] With more than 70,000 cases related to surgical pelvic repair products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining MDL cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record and the arguments of counsel.

also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Finally, in several of the instant *Daubert* motions, a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies. "Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262. The Fourth Circuit has stated that:

> A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter:

> A differential diagnosis that fails to take serious account of other potential causes

> may be so lacking that it cannot provide a reliable basis for an opinion on causation. However, "[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." The alternative causes suggested by a defendant "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," unless the expert can offer "no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause."

Id. at 265–66 (internal citations omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

Before I review these motions, I begin by addressing three arguments that apply to many of the parties' *Daubert* objections. Unless otherwise necessary, I will not address these objections again specific to each challenged expert. First, as I have maintained throughout these MDLs, I will not permit the parties to use experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's state of mind or on whether a party acted reasonably. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 702–03 (S.D. W. Va. 2014); *Lewis et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.

Second, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). I have diligently applied this rule to previous expert testimony, and I continue to adhere to it in this case. I will not parse the expert reports and depositions of each expert in relation to these same objections. I trust that able counsel in this matter will tailor expert testimony at trial accordingly.

Last, with respect to the arguments that certain experts' testimony is litigation driven, I note that an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion. *See Daubert v. Merrell Dow Pharm., Inc.* ("*Daubert II*"), 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture."). This concern, however, does have a role in applying *Daubert*. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007) (considering in the *Daubert* analysis "[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" (quoting Fed. R. Evid. 702 advisory committee's note)). In sum, I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. But I will consider the independence of an expert's testimony as evidence that his "research comports with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Having addressed these universal objections, I now turn to Cook's *Daubert* motions.

III. Cook's *Daubert* Motions

In this case, Cook seeks to exclude the expert opinions of Donald Kreutzer, Ph.D., Lisa Morici, Ph.D., and Daniel S. Elliott, M.D.

A. Motion to Exclude the Opinions and Testimony of Donald Kreutzer, Ph.D.

Dr. Kreutzer is a professor of surgery and the director of the Center for Molecular Tissue Engineering at the University of Connecticut School of Medicine. (Kreutzer Report [Docket 36-1], at 1). His current research focuses on immunology, inflammation, and wound healing, specifically in the area of tissue response to surgically implanted devices, including biologic surgical mesh. (*Id.* at 2–3).[3] Cook objects to the following opinions set forth in Dr. Kreutzer's expert report: (1) Injuries to women implanted with Cook products were caused "by a lack of quality control in Cook's product testing, manufacturing, and physician and patient product warnings"; (2) Cook products "cause excessive scarring and inflammation"; (3) "Cook did not conduct adequate testing of the products at issue"; (4) "Cook did not have adequate quality assurance procedures for the sourcing and manufacturing of the products"; and (5) Cook "did not adequately educate and warn patients and physicians on the products." (Cook's Mot. to Exclude the Ops. & Test. of Donald Kreutzer, Ph.D. [Docket 36], at 1–2). Cook also asks the court to exclude Dr. Kreutzer's opinions on Cook's corporate knowledge, motives, or intent, as well as any opinions in the form of legal conclusions. (*Id.* at 2).

The plaintiff clarifies that Dr. Kreutzer will not render the first, third, fourth, or fifth opinions listed above. (Pl.'s Opp. to Cook's Mot. to Exclude the Ops. & Test. of Donald Kreutzer, Ph.D. ("Pl.'s Opp. re: Kreutzer") [Docket 51], at 4 (confirming that Dr. Kreutzer will not testify as to the opinions challenged by Sections III(A), (C), (D), and (E) of Cook's

[3] Cook has moved to preclude the plaintiff from referring to Cook's SIS products as "mesh." (Cook's Initial Mots. *in Limine* [Docket 71], at 32). I will address this motion at a later time, and for purposes of this Memorandum Opinion and Order, I simply refer to the product in the way that the respective expert has referred to it.

memorandum)). Furthermore, the plaintiff has confirmed that Dr. Kreutzer will not testify about Cook's state of mind, intent, or knowledge, nor will he make legal conclusions at trial. Instead, Dr. Kreutzer will limit his testimony to his opinion that Cook's products cause inflammation, scarring, and tissue damage. In light of this clarification, I review Cook's *Daubert* challenge to this opinion only, and I **DENY as moot** the remainder of its motion concerning Dr. Kreutzer.

Cook moves to exclude Dr. Kreutzer's opinion that the inflammatory response to biologic mesh is "chronic" and "excessive" on the grounds that this opinion lacks a reliable basis.[4] In Cook's view, none of the scientific or medical studies cited by Dr. Kreutzer validate a finding of excessive or chronic inflammation of tissue, and as such, these studies cannot provide a scientific foundation for his opinion that meets the standards of *Daubert*. I do not agree with this reasoning. As an initial matter, Cook's interpretation of these articles as unrelated to excessive inflammation is, to put it mildly, subject to debate. Indeed, several of the articles, some written by Dr. Kreutzer himself, report findings of excessive inflammation resulting from the use of SIS material in vivo. (*See, e.g.*, Cook's Ex. 4, J.E. König et al., *Severe postoperative inflammation following implantation of a Stratasis sling*, Urology (2004) (concluding that the inflammatory reactions experienced by a woman implanted with a SIS pelvic repair product were "severe" and "considerable"); Pl.'s Ex. 3, D.L. Kreutzer et al., *Comparative analysis of histopathologic responses to implanted porcine biologic meshes*, Pub. Med. (2014) (finding "pronounced inflammatory responses" after a twelve-week study of the impact of biologic mesh on tissue); *see also* Kreutzer Report [Docket 36-1], at 3–4 (listing his research publications on biologic mesh)). And although none of the articles expressly describe the inflammation as "chronic" or "long-

[4] Cook does not appear to challenge Dr. Kreutzer's expertise with respect to this opinion. In any event, given Dr. Kreutzer's extensive education and experience in immunology and immunopathology, (*see* Kreutzer Report [Docket 36-1], 2–4 (listing Dr. Kreutzer's education, publications, professorships, and research in these areas)), I find him qualified to opine on the inflammatory response to biologic materials.

term," one could reasonably conclude, as Dr. Kreutzer does, that the results of the short-term studies signify that the inflammation could persist indefinitely. (*See* Kreutzer Dep. [Docket 51-2], at 87:17–20 (explaining his work, *Activation of Human Mononuclear Cells by Porcine Biologic Meshes in Vitro*, in which Dr. Kreutzer compared different graft materials in vitro and discovered certain "hallmark cells that are present, particularly in chronic inflammation," and "[are] associated with these grafts in chronic inflammation")).

To be sure, the conclusions reached in the articles do not seamlessly align with the conclusions proffered by Dr. Kreutzer. But, as demonstrated above, the articles relied upon by Dr. Kreutzer could plausibly be interpreted in a way that supports his opinions on chronic and excessive inflammation. The "analytical gap between the data and the opinion," if any, is not so great that the opinions must fall under *Daubert*. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Put simply, Cook's *Daubert* motion against Dr. Kreutzer boils down to a debate over the correct way to construe the scientific studies. As the gatekeeper of expert testimony, however, I must not concern myself with the "correctness of the expert's conclusions" and should instead focus on the "soundness of his methodology." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("*Daubert II*"); *see also United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) ("The court need not determine that the proffered expert testimony is irrefutable or certainly correct."). Here, Dr. Kreutzer considered and analyzed scientific articles and studies—some of which he authored—to reach his opinion that the implantation of biologic materials can cause chronic and severe inflammation. Thus, seeing no challenge to the methodologies used in the studies, I find that they provide a reliable, scientific basis for Dr. Kreutzer's opinions. *See Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008) ("[N]umerous courts have held that reliance on scientific test results prepared by others may

constitute the type of evidence that is reasonably relied upon by experts."). Any inconsistencies or discrepancies in his testimony go to its weight, not its admissibility, and Cook is free to capitalize on these matters during cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Cook also makes the blanket argument that "Dr. Kreutzer provided no testimony that would indicate his opinions are generally accepted by the scientific community." (Mem. in Supp. of Mot. to Exclude the Ops. & Test. of Donald Kreutzer, Ph.D. [Docket 37], at 7). While general acceptance "remains an important consideration" in evaluating expert testimony, this factor alone cannot necessitate or forbid exclusion. *United States v. Crisp*, 324 F.3d 261, 268 (4th Cir. 2003). As the Fourth Circuit explained,

> [t]he *Daubert* decision, in adding four new factors to the traditional "general acceptance" standard for expert testimony, effectively opened the courts to a broader range of opinion evidence than was previously admissible. Although *Daubert* attempted to ensure that courts screen out "junk science," it also enabled the courts to entertain new and less conventional forms of expertise. As the Court explained, the addition of the new factors would put an end to the "wholesale exclusion [of expert testimony based on scientific innovations] under an uncompromising 'general acceptance' test." *Daubert*, 509 U.S. at 596.

Id. at 268. Therefore, I do not find the general-acceptance factor as determinative here, given that Dr. Kreutzer's methodology in reaching his opinions is otherwise reliable. *See, e.g.*, *Daubert II*, 43 F.3d at 1322 n.11 ("Of course, the fact that one party's experts use a methodology accepted by only a minority of scientists would be a proper basis for impeachment at trial."). Cook's Motion to Exclude the Opinions and Testimony of Donald Kreutzer, Ph.D., [Docket 36] is accordingly **DENIED**.

B. Motion to Exclude the Opinions and Testimony of Lisa Morici, Ph.D.

Cook next moves to exclude the opinions of Dr. Lisa Morici, an immunologist and assistant professor of microbiology and immunology at Tulane University School of Medicine. In this case, Dr. Morici offers opinions on the use of porcine SIS biomaterials for treatment of POP and SUI, as well as "the complications resulting from transvaginal insertion and use," such as "foreign body reaction, acute and chronic inflammatory responses, acute and chronic infections, mesh erosion, degradation, [] weakening, and graft rejection and failure." (Morici Report [Docket 50-2], at 4). Cook objects to several portions of Dr. Morici's expert report. These objections fail for the same reasons explained in the court's opinion with respect to Dr. Kreutzer.

First, Cook challenges the reliability of Dr. Morici's opinion that Cook's products induce foreign body reaction. Cook states that Dr. Morici's opinions "go[] beyond the findings of the literature on which she relies." (Mem. in Supp. of Mot. to Exclude the Ops. & Test. of Lisa Morici, Ph.D. ("Cook's Mem. re: Morici") [Docket 39], at 7). Then, Cook proceeds to critique some of the cited articles, maintaining that animal studies and case reports cannot support an expert opinion on causation. While I agree that animal studies and case reports do not by themselves conclusively "demonstrate causation between SIS and foreign body reactions in patients," (Reply Mem. in Supp. of Mot. to Exclude the Ops. & Test. of Lisa Morici, Ph.D. ("Cook's Reply re: Morici") [Docket 58], at 7), it does not follow, as Cook suggests, that an expert's reliance on these works renders her opinion inadmissible under *Daubert*, especially when she has relied on other sources to reach the opinion. *See, e.g.*, *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am., UAW v. Johnson Controls, Inc.*, 499 U.S. 187, 222 (1991) (White, J., concurring) ("[T]he [lower] court should not have discounted the evidence as 'speculative' [citation omitted] merely because it was based on animal studies. . . . "); *Rider v.*

Sandoz Pharm. Corp., 295 F.3d 1194, 1199 (11th Cir. 2002) (stating that case reports "may support other proof of causation," even if they "alone ordinarily cannot prove causation").

In *Decker v. GE Healthcare Inc.*, for example, the Sixth Circuit affirmed the district court's decision to admit an expert's theory over a *Daubert* motion, given that the expert based his theory on "research conducted by scientists and doctors performing animal studies, *in vitro* studies, *in vivo* studies, human clinical studies and retrospective case studies along with review of the relevant published scientific and medical studies[.]" 770 F.3d 378, 392–93 (6th Cir. 2014).[5] Dr. Morici has similar research to back her opinions. First, she performed laboratory tests on rats, exposing them to SIS contaminated with live bacteria to evaluate its behavior *in vivo*. She observed "intense inflammatory response." (Morici Report [Docket 50-2], at 12–13). These results, as Dr. Morici explains in her report, "characterize" the foreign body reaction and are mirrored by animal tests performed by other researchers. (*See id.* at 6–8 (referring to the Petter-Puchner study performed on rats and the Rabah et al. study performed on rabbits, both of which reported foreign-body-like reactions that resulted in chronic inflammation)). Dr. Morici also considered a study performed on humans, in which the authors "showed SIS to be the most inflammatory biologic material when tested against human donor cells *in vitro* and *in vivo* in the rat model. . . . And, as I mentioned, [inflammatory reactions] are the hallmarks of the foreign body response." (Morici Dep. [Docket 50-3], at 139:19–140:5 (citing to the Bryan et al. study from 2012)). Finally, Dr. Morici referred to case studies that reported foreign body response to a sling made from SIS material. (*Id.* at 7–8 (citing to the Ho study and the John et al. study)).

[5] In *Decker*, the expert's theory was that gadolinium-based contrast agents used to produce MRI images can cause nephrogenic systemic fibrosis. *Decker*, 770 F.3d at 383–84. This causation opinion is analogous to Dr. Morici's opinion in this case—that SIS material can cause a foreign body reaction and subsequent tissue inflammation—and as such, I find the *Decker* case instructive.

Taken together, Dr. Morici has a well-rounded, scientific basis for her opinion that SIS products induce foreign body reactions. Her theory has been tested, by herself and others, as explained above, and the studies she relies upon have been subjected to the peer-review process. (*See generally* Morici Report [Docket 50-2]). This is enough to get through *Daubert*'s gates. *See Daubert*, 509 at 594–94 (holding that in reviewing expert testimony, the "overarching subject is the scientific validity"); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (explaining that whether a theory has been tested and whether it has been subjected to peer review, among other considerations, "may bear on a judge's determination of the reliability of an expert's testimony"). The fact that "differing research findings" exist or that "foreign body reactions are 'highly variable,'" (Cook's Reply re: Morici [Docket 58], at 8), goes to the weight of testimony and can be addressed during cross-examination of Dr. Morici. *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) ("[Under *Daubert*, t]he court need not determine that the proffered expert testimony is irrefutable or certainly correct.").

Cook raises similar objections to Dr. Morici's opinion that Cook products induce a chronic inflammatory response. Dr. Morici defines "chronic inflammation" as inflammation lasting three months or more. (Morici Dep. [Docket 50-3], at 52:22–25). Cook argues that none of the studies relied on by Dr. Morici report such persistent inflammation in humans. Dr. Morici, however, identified several such studies during her deposition. The Franklin study followed patients who had received SIS implants over five years and reported the presence of seromas, which, in Dr. Morici's view, "would indicate an imbalance in the tissue" and therefore chronic inflammation. (*Id.* at 183:21–184:8). The Uneo study, which followed patients for fifteen months, reported a recurrence rate of 30%, and in Dr. Morici's opinion, the recurrence could likely have been caused by chronic inflammation. (*Id.* 184:3–18). Dr. Morici also referred to

several internal studies performed by Cook, which collected data on patient complications for over two years and, from Dr. Morici's understanding, indicate the presence of chronic inflammation in these patients. (*Id.* at 185:3–16 ("[A]s an immunologist I have a difficult time reconciling that there's [sic] complications without inflammation.")).

While the conclusions reached in these tests do not seamlessly align with the conclusions proffered by Dr. Morici, as was the case with Dr. Kreutzer, *Daubert* does not require such precision. Rather, the *Daubert* inquiry is a "flexible one" that must be based "solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 580. Here, Dr. Morici reached her opinions about chronic inflammation based on her experience and work as an immunologist, as well as her reasoned interpretation of scientific, peer-reviewed literature. Other courts have accepted this methodology as reliable, *see Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008) (listing relevant cases), and in regard to Dr. Morici, I concur with these courts.

Finally, Cook argues that "Dr. Morici is not qualified to critique the procedures employed in preparing Cook's Biodesign products as she has no knowledge or expertise in this area." (Cook's Mem. re: Morici [Docket 39], at 10). The plaintiff agrees that Dr. Morici should not testify regarding this matter, given that she "could not testify, with certainty, that the problems with SIS mesh that she cites are the result of these manufacturing issues." (Pl.'s Opp. to Mot. to Exclude the Ops. & Test. of Lisa Morici, Ph.D. [Docket 50], at 10). But the plaintiff asks that the court allow the testimony if "defendants open the door to it." (*Id.*). I decline to make this reservation. Dr. Morici has not demonstrated experience in the field of product manufacturing or in the preparation of biomaterials for sale, as the plaintiff willingly admits, and as such, I **EXCLUDE** any testimony on this matter. *See* Fed. R. Evid. 702 (allowing for expert opinions if

the witness "is qualified as an expert by knowledge, skill, experience, training, or education"). I **GRANT** Cook's motion on this limited issue. The motion is otherwise **DENIED**.

C. Motion to Exclude the Opinions and Testimony of Daniel S. Elliott, M.D.

Cook seeks to exclude the expert opinions of Daniel S. Elliott, M.D. Dr. Elliott is an Associate Professor of Urology at the Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. Broadly, Dr. Elliott opines that SIS-based products cause a foreign body reaction, which leads to inflammation and contraction and results in acute and chronic pain. (Pl.'s Opp. to Cook's Mot. to Exclude the Ops. & Test. of Daniel Elliott, M.D. ("Pl.'s Opp. re: Elliott") [Docket 49], at 3). Specifically, Cook seeks to exclude the following expert opinions offered by Dr. Elliott: (1) SIS causes chronic inflammation which results in chronic pelvic pain, vaginal pain, and chronic dyspareunia; (2) SIS may cause an allergic and hypersensitive response, including delayed hypersensitivity; (3) One may extrapolate that contraction of SIS causes pain; and (4) Cook's prelaunch studies and IFU were inadequate. (Cook's Mot. to Exclude the Ops. & Test. of Daniel S. Elliott, M.D. [Docket 40], at 1–2).

1. Unsupported by the Evidence

First, Cook argues Dr. Elliott's opinion that SIS causes chronic inflammation, which results in chronic pain, is inadmissible because it is not supported by the evidence. (Cook's Mem. in Supp. of Mot. to Exclude the Ops. & Test. of Daniel S. Elliott, M.D. ("Cook's Mem. re: Elliott") [Docket 41], at 4). Although Dr. Elliott cites multiple scientific articles in support of his inflammation opinions, Cook contends these opinions are unreliable because none of the studies reporting inflammation in humans was long-term. As both parties have made clear through the briefing, there is simply not the same amount of scientific literature available on SIS as there is on other treatments, such as those involving polypropylene mesh. Dr. Elliott used the available

literature, which provides evidence of an inflammatory response, to support his theory that "[o]nce the inflammatory process begins, a cascade of events will occur which lead[s] to pelvic muscle pain and nerve irritation." (Elliott Report [Docket 49-1], at 35–36). Furthermore, Dr. Elliott's inflammation opinions are also based on his clinical experience with women whose bodies have rejected SIS products, as well as his own patients. (Pl.'s Opp. re: Elliott [Docket 49], at 5). On cross-examination, Cook may certainly highlight the fact that Dr. Elliott relied on short-term studies. However, this argument does not sufficiently undermine the reliability of Dr. Elliott's methodology under *Daubert*.

With regard to Dr. Elliott's opinions on allergic response and contraction, Cook objects to his reliance on studies that did not look specifically at Cook products. However, "expert testimony need not be based upon identical case studies or epidemiological data." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1384 (4th Cir. 1995) (citing *City of Greenville v. W.R. Grace & Co.*, 827 F.2d 975 (4th Cir. 1987)) (internal quotation marks omitted). I agree with the plaintiff "that the defendant should not be allowed to escape liability simply . . . because there are, as yet, no epidemiological studies concerning the health risks associated with" SIS products. *Id.* At this stage, I will allow Dr. Elliott's "extrapolations" because they are based on reliable data and he utilizes methodologies typically applied in his field. *See Doe v. Northwestern Mut. Life Ins. Co.*, No. 2:10-cv-02961, 2012 WL 1533104, at *4 (D.S.C. May 1, 2012) (permitting extrapolation, "especially in the areas of cutting edge science"). Accordingly, Cook's motion with regard to Dr. Elliott's inflammation, allergic response, and contraction opinions is **DENIED**.

2. Scientific Literature

Next, Cook contends that Dr. Elliott fails to consider and account for contrary scientific

literature. (Cook's Mem. re: Elliott [Docket 41], at 10). Cook's argument on this issue consists mostly of a summary of various articles, which in no way assists the court's *Daubert* determination. Furthermore, as the plaintiff points out, these articles are not cited by any of Cook's experts in their reports, which leads me to question their significance. (*See* Pl's Opp. re: Elliott [Docket 49], at 12). In *Tyree v. Boston Scientific Corporation*, I found Dr. Margolis's methodology unreliable because he rejected numerous studies without *any* scientific basis for doing so. *See* __ F. Supp. 3d __, *7 (S.D. W. Va. 2014), *available at* 2014 WL 5320566.. Here, Dr. Elliott provided a declaration detailing his review and subsequent rejection of the nine articles Cook discusses in its *Daubert* motion. (*See generally* Decl. of Dr. Daniel S. Elliott, M.D. [Docket 49-18]). The literature cited in Dr. Elliott's original report demonstrates sufficient indicia of reliability, and whether Dr. Elliott failed to review these particular articles goes to the weight of his testimony, not its admissibility. Dr. Elliott's declaration further forecloses Cook's argument. Accordingly, Cook's motion with regard to scientific literature is **DENIED**.[6]

3. Knowledge, Motive, or Intent

Next, Cook argues that Dr. Elliott may not testify concerning company knowledge, motive, or intent. (Cook's Mem. re: Elliott [Docket 41], at 16). The plaintiff concedes that Dr. Elliott will not testify about (1) Cook's state of mind, intent or knowledge; or (2) legal standards or legal conclusions. (Pl.'s Opp. re: Elliott [Docket 49], at 14). Accordingly, Cook's motion with regard to knowledge, motive, or intent is **DENIED as moot**.[7]

[6] As discussed more fully *infra* related to Dr. Atala, any supplemental information must be disclosed at least thirty days before trial. Fed. R. Civ. P. 26(e). Dr. Elliott's declaration [Docket 49-18] was filed on February 19, 2015, and is timely. Therefore, I consider it along with his original expert report.

[7] Based on the court's most recent experience with Dr. Elliott as a witness, I caution the plaintiff against using him to introduce corporate evidence. (*See* Trial Tr., No. 2:13-cv-22473 [Docket 337], at 153–55 ("[M]edical expert witnesses ought to be giving medical expert opinions. And under Rule 702 and Rule 703, statements by corporate representatives are not statements that a medical expert such as Dr. Elliott would reasonably rely upon in any context other than litigation. This is an important factor in my decision. . . . Accordingly, offering such evidence

4. Product Warnings and Labeling

Next, Cook contends Dr. Elliott is not qualified to opine on product warnings or labels. (Cook's Mem. re: Elliott [Docket 41], at 18). In response, the plaintiff explains that "Dr. Elliott will not discuss defendants' warnings in a regulatory context." (Pl.'s Opp. re: Elliott [Docket 49], at 15). Instead, "Dr. Elliott's report identifies particular risks with SIS biomaterials and explains that the IFU and defendant's product literature fails to disclose these risks." (*Id.*). I agree with the plaintiff that a urologist like Dr. Elliott is qualified to make this comparison. *See Wise v. C. R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *9–10 (S.D. W. Va. Feb. 7, 2015) (finding a urogynecologist qualified to opine on product labeling based on his knowledge and clinical experience); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D. W. Va. 2014) (finding a urologist qualified to opine on the risks of implanting a product and whether those risks were adequately expressed on the product's IFU). Relying on the plaintiff's assurance that Dr. Elliott's testimony will be limited to an evaluation of Cook's warnings based on his knowledge of and clinical experience with the risks of SIS products—and not on FDA requirements or regulations—Cook's motion with regard to product warnings and labeling is **DENIED**.

5. Adequacy of Testing

Lastly, Cook argues Dr. Elliott is not qualified to opine on the adequacy of Cook's product testing and that his expert opinions on this subject are unreliable. (Cook's Mem. re: Elliott [Docket 41], at 19). The plaintiff concedes that "Dr. Elliott will not testify that defendant had an obligation to study and failed to do so." (Pl.'s Opp. re: Elliott [Docket 49], at 16). Accordingly, Cook's motion with regard to adequacy of testing is **DENIED as moot**.

---

through this witness, through this doctor substantially increases the risk of confusing and misleading this jury. . . . I am not going to allow Dr. Elliott to further opine based on what corporate representatives said.").

In sum, Cook's motion with regard to Dr. Elliott is **DENIED in part** and **DENIED as moot in part**.

IV. Plaintiff's *Daubert* Motions

A. Motion to Exclude General Liability/Causation Testimony of Anthony Atala, M.D.

Dr. Anthony Atala is a practicing urologist and a professor in urology at the Wake Forest University School of Medicine. Over the past ten years, Dr. Atala has performed pelvic surgeries using SIS products manufactured by Cook. Based primarily on his personal experience with these products, along with a peer-reviewed study that he co-authored, Dr. Atala proffers that he "do[es] not see any capacity" of Cook's SIS products "to cause the injuries of which the plaintiffs generally complain." (Atala Report [Docket 30-1], at 5). The plaintiff raises two objections to this general causation opinion. First, she asserts that the court should exclude Dr. Atala's testimony because his expert report does not comply with the disclosure requirements set forth in Federal Rule of Civil Procedure 26. Second, she argues that Dr. Atala's opinion lacks supporting authority or methodology, and so it is inadmissible under *Daubert*. I address each objection in turn.

1. Federal Rule of Civil Procedure 26

In relevant part, Rule 26 provides as follows:

> *Witnesses Who Must Provide a Written Report.* Unless otherwise stipulated or ordered by the court, this disclosure must be accompanied by a written report—prepared and signed by the witness—if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony. The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authored in the

> previous 10 years; and (v) a statement of the compensation to be paid for the study and testimony in the case.

Fed. R. Civ. P. 26(a)(2)(B). If a report is incomplete or incorrect in some material respect, the party must supplement its report with the additional or corrective information. Fed. R. Civ. P. 26(e). Any supplemental information must be disclosed at least thirty days before trial. *Id.* (requiring additions or changes to expert disclosures to be disclosed "by the time the party's pretrial disclosures under Rule 26(a)(3) are due"). Dr. Atala provided the plaintiff with an expert report on November 16, 2014, and he supplemented his report with a sworn affidavit on February 18, 2015. (*See* Cook's Ex. 1 ("Atala Aff.") [Docket 46-1]). Trial is scheduled for May 18, 2015. Therefore, the supplemental affidavit is timely, and I consider it along with the initial expert report in determining the adequacy of the expert disclosure.[8]

The plaintiff argues that Dr. Atala's expert disclosure falls short of the Rule 26 requirements in that it "does not offer any reasoning or cite any remotely relevant supporting authority in support of his general causation opinions." (Pl.'s Mot. to Exclude General Liability/Causation Test. of Anthony Atala, M.D. ("Pl.'s Mot. re: Atala") [Docket 30], at 3–4). I disagree and find that Dr. Atala's expert disclosure adequately states his opinion and the authority supporting it for the purposes of Rule 26. He explains that he reviewed deposition testimony (Atala Report [Docket 30-1] at 2), his SIS patients' records from the past ten years (*Id.* at 5), a peer-reviewed study in which he participated on the long-term postoperative surgical complications of SIS implantation surgery (*id.* at 4–5), and medical literature on the use of biologic graft materials including Cook's SIS products (Atala Aff. [Docket 46-1], at 4). Dr. Atala also provided his *curriculum vitae*, which includes his educational background, professional

[8] I refer to Dr. Atala's initial expert report [Docket 19-1] and his supplemental affidavit [Docket 46-1] collectively as his "expert disclosure."

appointments, honors and awards, teaching experiences, and publications for the past twenty-five years. (*Id.*). This is enough to satisfy Rule 26, a discovery requirement simply meant to ensure that the opposing party has a "reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from other witnesses." Fed. R. Civ. P. 26 advisory committee notes; *see also Ciomber v. Coop. Plus, Inc.*, 527 F.3d 635, 642 (7th Cir. 2008) ("The purpose of Rule 26(a)(2) is to provide notice to opposing counsel [] as to what the expert witness will testify . . . . ").[9] But whether or not the supporting authority cited by Dr. Atala in his expert disclosure is enough to satisfy the reliability requirements of Federal Rule of Evidence 702—that it is relevant, scientifically valid, and supportive of the expert's opinions—is another matter. Thus, finding no Rule 26 error in Dr. Atala's expert disclosure, I now apply *Daubert*'s analysis to his opinions.

2. Reliability of Methodology

The plaintiff contends that the court should exclude Dr. Atala's opinions because they are conclusory statements with no supporting authority or scientific methodology. Consequently, in the plaintiff's view, Dr. Atala's report is comprised of improper *ipse dixit*, or "opinions justified solely by the fact that a qualified expert holds them." (Pl.'s Mot. re: Atala [Docket 30], at 4–5). Dr. Atala offers several bases for his opinion that SIS lacks the capacity to cause the injuries of which the plaintiff complains, and, contrary to the plaintiff's position, I find that these sources, taken together, create a reliable basis for his testimony.

Dr. Atala primarily refers to his experience as a urologist. He explains that over the past ten years, he has used SIS graft material manufactured by Cook in pelvic surgeries, and "[n]one

[9] Though the plaintiff does not point this out, I notice that Dr. Atala has not provided "a statement of compensation" for his testimony in this case as required by Rule 26(a)(2)(B). I find this omission a harmless error, but, in the interest of conformance with Rule 26, I **ORDER** Cook to provide compensation information to the plaintiff within **seven days** of the entry of this Memorandum Opinion and Order.

of [his] patients showed any evidence of graft infection, erosion, chronic inflammation, allergic reactions, pain, or genitourinary problems." (Atala Report [Docket 30-1], at 5). In his supplementary affidavit, Dr. Atala elaborates that his practice involves "follow[ing] up" with his patients after their surgeries for a period of six months or more and advising them to "contact [him] if they experienced any problems, symptoms, or matters they felt were related to the surgery." (Atala Aff. [Docket 46-1], at 2). None of his patients reported any graft complications during follow-up visits or otherwise, which led him to his conclusion that the SIS grafts do not cause injury. (*Id.*). The plaintiff claims that clinical experience alone cannot serve as a basis for an expert opinion.

The advisory committee notes to Federal Rule of Evidence 702 offer some insight into this issue, explaining that "[i]n certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony." Fed. R. Evid. 702 advisory committee notes. Indeed, as the Supreme Court has observed, "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999). When an expert relies "solely or primarily on experience," however, the court cannot simply "tak[e] the expert's word for it." Fed. R. Evid. 702 advisory committee notes. Rather, the *Daubert* inquiry becomes whether the expert can "explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Id.*; *see also Kumho Tire Co.*, 526 U.S. at 151 ("[I]t will at times be useful to ask even of a witness whose expertise is based purely on experience, say, a perfume tester able to distinguish among 140 odors at a sniff, whether his preparation is of a kind that others in the field would recognize as acceptable."). Thus, the plaintiff is correct that the court cannot deem an opinion reliable on the

grounds that the expert has experience, unless the expert has established a link between his observations and his conclusions.

Dr. Atala's report, however, offers more than a bald appeal to his experience. In addition to examining his ten years' of practice with Cook's SIS material, Dr. Atala also relied on a peer-reviewed study in which he participated to reach his conclusions in this case. (*See* Atala Report [Docket 30-1], at 4–5 (referring to Raya-Rivera et al., *Tissue-engineered autologous vaginal organs in patients: a pilot cohort study*, 384 Lancet 329 (2014))). In this study, the authors used SIS material in vaginal reconstruction surgeries and followed the patients over an eight-year period. The authors found "no long-term postoperative surgical complications." Raya-Rivera et al. at 329. According to Dr. Atala, the study's results reflect what he has observed in his own patients—SIS products have the ability "to remodel in the pelvic/vaginal area of the human body" and that patients "d[o] not suffer from any long-term adverse effects from the SIS product like or similar to those claimed by the plaintiff in the Cook cases." (Atala Aff. [Docket 46-1], at 3).[10] Dr. Atala's thorough comparison of his experience to a reliable and relevant peer-reviewed study—published in one of the world's leading medical journals—is enough to open *Daubert*'s gates. *See, e.g.*, *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *72 (S.D. W. Va. 2014), *as amended* (Oct. 29, 2014), *available at* 2014 WL 5320566 (finding that Dr. Green's clinical experience and review of the scientific literature, which he explained and cited throughout his expert report, "are sufficiently reliable bases in forming this particular opinion").[11]

[10] That this study was performed on women with vaginal aplasia (the absence of a normal vagina at the time of birth) does not make it irrelevant, as the plaintiff suggests, because the conclusion of the study—that the use of biomaterial in vaginal reconstruction "remains functional in a clinical setting long term"—is universal. Raya-Rivera et al. at 336. The selection of women with vaginal aplasia was merely for the purpose of uniformity across subjects. *See id.* at 335.

[11] Dr. Atala also connects his opinions with the research of others. (*See* Atala Aff. [Docket 46-1], at 4 (listing six other articles that "are consistent with and supported by" the Raya-Rivera et al. study)). For the reasons explained

The plaintiff has some questions that are left unanswered by Dr. Atala's expert report. But these questions, which concern the particulars of Dr. Atala's analysis and opinions, are better suited for deposition or cross-examination. As the Fourth Circuit explained, "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable (i.e. based on 'scientific knowledge') and helpful (i.e. of assistance to the trier of fact in understanding or determining a fact in issue)." *Md. Case. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Here, I find Dr. Atala's testimony, which arises from scientific knowledge gleaned from his experience as a urologist and his work on the Raya-Rivera et al. study, as reliable and helpful to the jury's determination of causation. Therefore, I **DENY** the plaintiff's Motion to Exclude General Liability/Causation Testimony of Anthony Atala, M.D. [Docket 30].

B. Motion to Exclude General Liability/Causation Testimony of Mickey Karram, M.D.

Dr. Mickey Karram, a practicing urologist and professor of obstetrics and gynecology at the University of Cincinnati School of Medicine, opines that his experience and the "documented feature" of SIS material "is in direct contradiction to the alleged complaints that the material [] is incompatible or not safe." (Karram Report re: Dunnington [Docket 31-1], at 2; Karram Report re: Gann [Docket 31-2], at 2). The plaintiff moves to exclude Dr. Karram's opinions on the basis that the sole general-causation paragraph in his reports does not comply with the disclosure requirements of Federal Rule of Civil Procedure 26, nor does it demonstrate reliability as required by *Daubert*.

To begin, I note that the bulk of Dr. Karram's reports focus on specific causation for two

---

below with respect to Dr. Karram, I do not consider this literature in my analysis of his expert opinions. *See infra* at 28.

women who are not parties to this case. (Karram Report re: Dunnington [Docket 31-1] (opining on specific causation for Ms. Sara Dunnington); Karram Report re: Gann [Docket 31-2] (opining on specific causation for Ms. Carol Gann)). These opinions are irrelevant to the present matter and thus **EXCLUDED**. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and ergo, non-helpful." (internal quotations omitted)). Accordingly, the remainder of my discussion focuses on the single general-causation paragraph in Dr. Karram's reports, (*see* Karram Report re: Dunnington [Docket 31-1], at 3; Karram Report re: Gann [Docket 31-2], at 2), along with the supplemental affidavit provided by Cook in response to the plaintiff's motion, (*see* Cook's Ex. 1 ("Karram Aff.") [Docket 43-1]).

1. Federal Rule of Civil Procedure 26

In relevant part, Rule 26 provides as follows:

> *Witnesses Who Must Provide a Written Report.* Unless otherwise stipulated or ordered by the court, this disclosure must be accompanied by a written report—prepared and signed by the witness—if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony. The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years; and (v) a statement of the compensation to be paid for the study and testimony in the case.

Fed. R. Civ. P. 26(a)(2)(B). If a report is incomplete or incorrect in some material respect, the party must supplement its report with the additional or corrective information. Fed. R. Civ. P. 26(e). Any supplemental information must be disclosed at least thirty days before trial. *Id.* (requiring additions or changes to expert disclosures to be disclosed "by the time the party's pretrial disclosures under Rule 26(a)(3) are due"). Here, in addition to his expert reports regarding Ms. Dunnington and Ms. Gann, Dr. Karram provided a supplemental sworn affidavit

regarding his opinions on February 17, 2015. (*See* Karram Aff. [Docket 43-1]). Trial is scheduled for May 18, 2015. Therefore, the supplemental affidavit is timely, and I consider it along with the initial expert report in determining the adequacy of the expert disclosure.[12]

The plaintiff argues that Dr. Karram's expert disclosure falls short of the Rule 26 requirements in that it "offers no supporting authority." (Pl.'s Mot. to Exclude General Liability/Causation Test. of Mickey Karram, M.D. ("Pl.'s Mot. re: Karram") [Docket 31], at 4). Although Dr. Karram's expert disclosure is cursory, I find that it adequately states his opinion and the authority supporting it for the purposes of Rule 26. He explains that his opinion was informed by his observations of and experience with SIS patients over the past five years (Karram Aff. [Docket 43-1], at 2–3), in addition to "well documented" literature (*id.* at 3–4). Dr. Karram also provided his *curriculum vitae*, which includes his educational background, medical experience, honors and awards, leadership positions, professorships, and publications for the past thirty years. (*Id.*). This is enough to satisfy Rule 26, a discovery requirement simply meant to ensure that the opposing party has a "reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from other witnesses." Fed. R. Civ. P. 26 advisory committee notes; *see also Ciomber v. Coop. Plus, Inc.*, 527 F.3d 635, 642 (7th Cir. 2008) ("The purpose of Rule 26(a)(2) is to provide notice to opposing counsel [] as to what the expert witness will testify . . . . "). But whether or not the supporting authority cited by Dr. Karram in his expert disclosure is enough to satisfy the reliability requirements of Federal Rule of Evidence 702—that it is relevant, scientifically valid, and supportive of the expert's opinions—is another matter. Thus, finding no Rule 26 error in Dr. Karram's expert disclosure, I now apply *Daubert*'s analysis to his opinions.

[12] I refer to Dr. Karram's initial expert reports [Dockets 31-1 & 31-2] and his supplemental affidavit [Docket 43-1] collectively as his "expert disclosure."

2. Reliability of Methodology

The plaintiff contends that the court should exclude Dr. Karram's opinions because they are conclusory statements with no identifiable supporting authority or scientific methodology. Consequently, in the plaintiff's view, Dr. Karram's expert disclosure is comprised of improper *ipse dixit*, or "opinions justified solely by the fact that a qualified expert holds them." (Pl.'s Mot. re: Karram [Docket 31], at 4–5). The limited information set forth in Dr. Karram's expert disclosure, though sufficient to get by the plaintiff's Rule 26 challenge, is not complete enough to make a reliability decision under *Daubert* at this time.

Dr. Karram primarily refers to his experience as a urologist in reaching his opinion. He states that during the last five years of his practice, he has used SIS in multiple pelvic floor surgeries, and his experience is "in direct contradiction" to the complaints raised against Cook. (Karram Aff. [Docket 43-1], at 3). While experience can be "the predominant, if not sole, basis for a great deal of reliable expert testimony," the court must ensure that the expert can "explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee notes. Generally, under this analysis, a doctor who has extensive experience with a medical device may offer opinions on the use of that device. But when the opinion crosses into causation, like Dr. Karram's, an unscientific sample of the expert's patients is not an adequate foundation to suggest reliability under *Daubert*, and the court needs further explanation from the expert on how his experience leads to a causation opinion in order to make a reliability determination.

Dr. Atala, for instance, provided the needed explanation by referring to and elaborating on his co-authored peer-reviewed study, which mirrored his observations as a pelvic surgeon and

established a reliable basis for his opinion on medical causation. Only equipped with Dr. Karram's abbreviated Rule 26 expert disclosure, the court cannot tell if Dr. Karram has a similar basis for his causation opinions. Dr. Karram points to "well documented" literature and provides a list of nine "consistent" articles in his affidavit. (Karram Aff. [Docket 43-1], at 2–4). Unlike Dr. Atala, however, he does not convey how he relied on these articles in reaching his opinions. Indeed, beyond listing them in his affidavit, he does not mention these articles in his expert disclosure at all. It is possible that he thoroughly read the authors' work and used their results to come to his opinion in this case. But the court has no way to reach an informed conclusion.[13] Put simply, without a more developed record, such as sworn testimony via deposition or interrogatories, the court cannot make an informed decision about the reliability of Dr. Karram's general causation opinions.

Therefore, the court **RESERVES** judgment on the plaintiff's motion with respect to Dr. Karram [Docket 31]. A short hearing (outside the presence of the jury) will be held on this matter at a convenient time during trial.

C. Motion to Exclude General Liability/Causation Testimony of Dennis Metzger, Ph.D.

The plaintiff seeks to exclude the general causation opinions of Dennis Metzger, Ph.D. Dr. Metzger is an immunologist who opines that there is no scientific evidence that SIS could cause graft-hose-disease ("GVHD"), hypersensitivity reactions, chronic or acute infections, or deleterious immune reactions. (Metzger Report [Docket 32-1], at 3). In forming his opinions, Dr.

[13] This determination is particularly difficult to make, given that Dr. Karram clearly copied and pasted the list of articles from Dr. Atala's affidavit. This is evident by Dr. Karram's statement that his opinions "are consistent with and supported by *our* study as discussed above." (Karram Aff. [Docket 43-1], at 4 (emphasis added)). Nowhere in his expert disclosure does Dr. Karram discuss a study in which he participated. Rather, this language came from Dr. Atala's expert disclosure, wherein he refers to the Raya-Rivera et al. study in which he participated as "our study." (Atala Aff. [Docket 46-1], at 5).

Metzger relies primarily on two studies he conducted specific to the use of SIS for tissue repair. I will refer to the first study as the "mouse study" and the second study as the "human study." In both studies, Dr. Metzger "found that SIS did indeed induce immune responses . . . but these responses were restricted to the so-called Th2 immune pathway, which is known to be consistent with tissue acceptance." (Metzger Report [Docket 32-1], at 1). The results of the mouse study were published in a peer-reviewed journal in 2001, and the results of the human study were published in a peer-reviewed journal in 2007. (*Id.* at 2). The plaintiff contends that Dr. Metzger's opinions are both irrelevant and unreliable. (Pl.'s Daubert Mot. to Exclude General Liability/Causation Test. of Dennis Metzger, Ph.D. ("Pl.'s Mot. re: Metzger") [Docket 32], at 2). More specifically, the plaintiff argues that the animal studies upon which Dr. Metzger relies cannot be "extrapolated to the plaintiff." (*Id.* at 4).

To begin, the plaintiff appears to confuse the issues of relevance and reliability, arguing "Dr. Metzger's opinions are neither relevant nor reliable because, quite simply, his analysis is too far removed from the issues in this case." (Pl.'s Mot. re: Metzger [Docket 32], at 3). Whether Dr. Metzger's analysis is "too far removed" relates to relevance, not reliability. *See Daubert*, 509 U.S. at 591–92 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."). In contrast, with regard to reliability, the court will focus on Dr. Metzger's "principles and methodology." *Id.* at 594–95.

1. Relevance

First, the plaintiff contends that Dr. Metzger's opinions are irrelevant because his "studies were not designed to (and did not) demonstrate whether there is an inflammatory reaction to SIS." (Pl.'s Mot. re: Metzger [Docket 21], at 3). In reviewing the materials in this case, I note that "immune response" and "inflammatory response" have been used somewhat

interchangeably. (*See* Metzger Dep. [Docket 56-2], at 66–67 (Q: [H]ow do you distinguish an immunological response from an inflammatory response? A: I don't. I don't necessarily distinguish those two terms."); *see also* Aff. of Dennis W. Metzger, Ph.D. [Docket 48-1], at 1 ("As indicated in my report, I have personally studied Cook porcine small intestinal submucosa ("SIS") and whether it elicits any immune or inflammatory response in both animal models and human, and, if so, the nature of any such responses.")). Regardless, Dr. Metzger's concise description of the mouse study adequately demonstrates its relevance: "So the question we had was, again: Was there an immune response to SIS in mice, and ultimately in humans? And was it the type of immune response which would be thought to lead to rejection of a foreign material such as SIS?" (Metzger Dep. [Docket 56-2], at 77–78). The plaintiff alleges that SIS is "biologically reactive with human tissue and promotes an immune response[,]" which "promotes infection and rejection of the biological mesh, as well as damage to the surrounding pelvic tissue." (Master Compl., MDL 2440 ¶ 24). Therefore, Dr. Metzger's examination of whether mice had an immune response to SIS, which resulted in rejection, fits squarely within the plaintiff's allegations. Accordingly, the plaintiff's motion with regard to relevance is **DENIED**.

2. Reliability

Next, the plaintiff contends that Dr. Metzger's opinions are unreliable because they are based solely on animal studies, which cannot be extrapolated to humans. In response, Cook argues in support of the validity of animal studies, but also explains that Dr. Metzger's opinions are based on "his overall scientific experience during thirty years of professional research, teaching and participation in professional organizations." (Cook's Resp. in Opp. to Pl.'s Daubert Mot. to Exclude the General Liability/Causation Test. of Dennis Metzger, Ph.D. ("Cook's Opp. re: Metzger") [Docket 48], at 7). Additionally, Cook filed an affidavit from Dr. Metzger further

explaining the different studies he has participated in,[14] as well as listing scientific literature not originally cited in his expert report that he relied upon in forming his opinions. (*See generally* Aff. of Dennis W. Metzger, Ph.D. [Docket 48-1]).[15]

Properly designed and conducted animal testing can yield relevant and useful information. *See Bourne ex rel. Bourne v. E.I. DuPont de Nemours & Co.*, 189 F. Supp. 2d 484, 496 (S.D. W. Va. 2002). However, "experts relying on animal studies 'must be prepared to explain how such studies can be reliably extrapolated to prove comparable effects in humans.'" *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680814, at *6 (S.D. W. Va. July 8, 2011) (quoting *In re Prempro*, 738 F. Supp. 2d 887, 894 (E.D. Ark. 2010)); *see also Decker*, 770 F.3d at 392 (affirming district court's finding that expert opinions based on animal studies, when combined with other scientific evidence, pass muster under *Daubert*). Had Dr. Metzger's opinions been based solely on the mouse study or if he failed to explain how and why the study can be extrapolated to humans, I would tend to question the reliability of his methodology. However, Dr. Metzger's deposition testimony and subsequent declaration explain that his opinions are based on both animal *and* human studies, as well as his review of scientific literature and years of experience as an immunologist. In fact, when describing the human study, Dr. Metzger explicitly states that it was conducted to see if he could achieve the same results with humans as he did with mice. (Metzger Dep. [Docket 56-2], at 81 ("We were trying to confirm the mouse studies basically.")). Dr. Metzger "extrapolated" his mouse results by actually performing a comparable study on humans. Taken together, I **FIND** that the different bases for Dr. Metzger's

[14] From 1996 to 2000, Dr. Metzger participated in three SIS symposiums in Florida where he presented his research. (Aff. Of Dennis W. Metzger, Ph.D. [Docket 48-1], at 1-2). Additionally, he acted as principal investigator for two SIS studies funded by Cook. He presented his Cook research at a scientific conference in Montreal, Quebec, Canada in 2004, and spoke at a symposium in New Mexico in 2005. (*Id.* at 4).

[15] As discussed more fully *supra* related to Dr. Atala, any supplemental information must be disclosed at least thirty days before trial. Fed. R. Civ. P. 26(e). Dr. Metzger's affidavit [Docket 48-1] was filed on February 19, 2015, and is timely. Therefore, I consider it along with his original expert report.

expert opinions satisfy the requirements of *Daubert*. Accordingly, the plaintiff's motion with regard to reliability is **DENIED**.

D. Motion to Exclude the Testimony of Dr. Stephen Park Rhodes

Dr. Stephen Rhodes offers opinion testimony on Cook's "compliance with the FDA regulations and guidance." (Rhodes Report [Docket 33-1], at 2). Specifically, Dr. Rhodes opines that Cook followed the standards and requirements for premarket clearance under 21 U.S.C. § 360 ("510(k) clearance") and ultimately obtained 510(k) clearance from the FDA for each of its SIS products.[16] The plaintiff moves to exclude Dr. Rhodes's opinion on the basis that purported compliance with FDA regulations is not relevant to the plaintiff's state law tort claims. As the plaintiff points out, this court has excluded FDA evidence in every MDL trial to date under Federal Rules of Evidence 401, 402, and 403. *See, e.g., Cisson v. C. R. Bard, Inc.*, __ F. Supp. 3d __, *4 (S.D. W. Va. 2015), *available at* 2015 WL 566959 (listing cases). I see no reason to depart from this position here.

Daubert advises courts to keep in mind the other rules of evidence when evaluating expert testimony. *See Daubert*, 509 U.S. at 595 ("Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules . . . ."). Accordingly, I first consider whether Dr. Rhodes's opinion on FDA compliance is relevant to the state tort claims in this case under Rule 401, which provides that evidence is relevant if "it has a tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401. Cook contends that its compliance with 510(k) goes to "whether the product is defective, whether the defective condition is unreasonably dangerous, and whether the defendant met the applicable standard of care." (Resp. in Opp. to Pl.'s Mot. to Exclude the

[16] For a discussion on the 510(k) clearance process, see *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014).

Test. of Dr. Stephen Park Rhodes ("Cook's Opp. re: Rhodes") [Docket 47], at 2). Cook points to the Restatement (Third) of Torts in support of its position, which provides that "a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective[.]" Restatement (Third) of Torts: Products Liability § 4 (1998). Given the Supreme Court precedent on the meaning and purpose of 510(k) clearance, however, Cook's argument must fail.

The Supreme Court has held that compliance with 510(k) focuses on "equivalence, not safety," and that products entering the market through the 510(k) process have "never been formally reviewed [for] safety and efficacy." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–79 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008) (explaining that the 510(k) process is an "exemption from federal safety review"). If 510(k) does not go to a product's independent safety and efficacy—the "very subjects" of the plaintiff's products liability claims, *id.* at 323—then evidence of Cook's compliance with 510(k) has minimal relevance in this case and should be excluded by the court. *See* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). The Restatement provision, which focuses on *safety* statutes, is thus inapplicable, *see* Restatement (Third) of Torts: Products Liability § 4 cmt. a (explaining that the phrase "safety statute or administrative regulation" is meant to encompass regulations "that establish binding safety standards for the design and marketing of products"), and Dr. Rhodes's opinion, which focuses entirely on 510(k) compliance, has no relevance in this case.[17]

[17] The cases that Cook lists in its response, wherein the court considered FDA compliance, are also not determinative here. Most of them concern the defectiveness of prescription drugs, which are governed by regulations that concern *safety*, thereby distinguishing them from the case at bar. *See, e.g., Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 589 (6th Cir. 2013) (considering a prescription drug and concluding that "[u]nless federal law bears on the state duty of care, evidence of such law is inadmissible"); *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 538 (6th Cir. 1993) (holding, prior to *Lohr*, that FDA approval of a new drug, which requires consideration of the drug's safety, can be considered by the jury in reaching its verdict on design defect) (emphasis added); *Rader v. Teva Parental Meds. Inc.*, 795 F. Supp. 2d 1143, 1149 (D. Nev. 2011) ("This court agrees . . . that compliance with product *safety*

Assuming 510(k) clearance satisfied the relevance standard of Rule 401, I nevertheless find that the balancing test set forth in Rule 403 forecloses the admission of FDA evidence and, consequently, Dr. Rhodes' opinion. Rule 403 permits exclusion of relevant evidence "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Here, expert opinions on the requirements of the Federal Drug and Cosmetic Act ("FDCA")—which are not at issue in the case—and Cook's compliance with § 510(k) of the FDCA—which says nothing about the independent safety of the product—could lead to more confusion about the state tort claims than enlightenment. As I explained in *Lewis v. Johnson & Johnson*:

> [a]dmission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims. The prejudicial value of evidence regarding the 510(k) process far outweighs its probative value. . . . Jurors are likely to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not. [Furthermore,] the jury may attach undue significance to an FDA determination and [] alleged shortcomings in FDA procedures are not probative to a state law products liability claim.

991 F. Supp. 2d 748, 754–55 (S.D. W. Va. 2014). Allowing such evidence to come in through the gloss of an expert opinion increases the Rule 403 concern because "[e]xpert evidence can be both powerful and quite misleading." *Daubert*, 509 U.S. at 595 (internal quotation marks

---

regulations is relevant and admissible on the question of defectiveness." (internal quotations omitted)) (emphasis added); *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010) (concluding that FDA approval of a drug, which requires consideration of the drug's safety, can be relevant to the negligent design claim); *Erickson v. Baxter Healthcare, Inc.*, 151 F. Supp. 2d 952, 958–59 (N.D. Ill. 2001) (concerning intravenous blood transfusions); *Brasher v. Sandoz Pharms. Corp.*, No. cv-98-TMP-2648-S, 2001 WL 36403362, at *1 (N.D. Ala. Sept. 21, 2001) (concerning a prescription drug called Parlodel, which was marketed through the FDA's premarket approval process); *Martinkovic v. Wyeth Labs., Inc.*, 669 F. Supp. 212, 217 (N.D. Ill. 1987) (considering a vaccine, which is governed by the National Vaccine Program, 42 U.S.C. § 300aa-22); *Foyle v. Lederle Labs.*, 674 F. Supp. 530, 533 (E.D.N.C. 1987) (same). The only case that focuses on a medical device was decided by a district court years prior to *Lohr*, *Hegna v. E.I. du Pont de Nemours & Co.*, 806 F. Supp. 822 (D. Minn. 1992), and consequently, it does not carry much weight in my analysis.

omitted). Introducing 510(k) evidence could also provoke the parties to engage in a time-consuming mini-trial on whether Cook in fact complied with its provisions. Excluding Dr. Rhodes's opinion testimony, as well as other FDA evidence, avoids these risks.

Cook's attempts to get around the court's previous holdings on this matter are not persuasive. First, Cook attempts to diminish the controlling law set forth in *Lohr* by pointing to an internal evaluation from the FDA, which expresses the view that that modifications to the 510(k) program over time have formed it into a "multifaceted premarket review process" that "provide[s] reasonable assurance of safety and effectiveness." (Resp. re: Rhodes [Docket 47], at 7 (quoting Ctr. For Device & Radiological Health, *510(k) Working Group Preliminary Report and Recommendations* 34 (2010))). Given the Supreme Court's clear analysis in *Lohr*, I decline to give this internal evaluation any deference. The FDA cautions that the internal reports are "preliminary" and do not reflect any "decisions on specific changes to pursue." Jeffrey Shuren, Director, Ctr. for Devices & Radiological Health, *Foreword: A Message from the Center Director* 5 (2010). Thus, while cognizant of these recommendations, I must defer to the current Code of Federal Regulations and Supreme Court precedent, both of which consistently maintain that 510(k) clearance does not focus on product safety. *See Lohr*, 518 U.S. at 493 (1996) ("[T]he 510(k) process is focused on equivalence, not safety."); 21 C.F.R. § 807.97 (2012) (providing that 510(k) clearance "does not in any way denote official approval of the device" and "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding").[18]

[18] Furthermore, the most recent FDA commentary on 510(k) clearance, published after the internal evaluation, indicates concurrence with these authoritative sources. *See generally* FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff* ("Guidance Document") (July 28, 2014), *available at* http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm284443.htm (last visited Mar. 19, 2015). Crucially,

In its next attempt to convince the court of the relevancy of Dr. Rhodes's FDA opinion, Cook contends that Dr. Rhodes's testimony "is relevant on the issue of federal preemption," and it spends the rest of its brief arguing that the court should "entitle" Cook's SIS products to federal preemption. (Cook's Opp. re: Rhodes [Docket 47], at 4). An argument in favor of preemption does not belong in the context of *Daubert*. Indeed, whether federal law preempts a state claim is a question of law for the court to decide and not for an expert to comment on. *See Nat'l Home Equity Mortg. Ass'n v. Face*, 64 F. Supp. 2d 584, 591 (E.D. Va. 1999), *aff'd*, 239 F.3d 633 (4th Cir. 2001) ("The Supreme Court has expressly stated that federal preemption of contrary state laws presents pure questions of law . . . ." (citing *United Steelworkers of Am. v. Rawson*, 495 U.S. 362, 365 (1990))). Accordingly, Dr. Rhodes's testimony is not relevant to the determination of whether 510(k) clearance preempts any state law claims.

In sum, even if Dr. Rhodes's opinions on 510(k) compliance met the relevance requirements set forth in Rule 401, the substantial risk of misleading the jury and wasting judicial resources by diving into a morass of FDA regulations—none of which relate to the state law claims at issue—weighs heavily in favor of exclusion. For these reasons, Dr. Rhodes's opinion is **EXCLUDED** in its entirety, and the plaintiff's Motion to Exclude the Testimony of Dr. Stephen Park Rhodes [Docket 33] is **GRANTED**.

---

the Guidance Document distinguishes between the vigorous analysis of product safety conducted under the premarket approval process and the more lax "evidentiary standard" applied in the 510(k) review process. *Id.* at 7. For premarket approval, the medical device must independently demonstrate safety and effectiveness. *Id.* at 6. In contrast, for 510(k) review, the FDA considers safety and effectiveness comparatively, "generally rel[ying], in part, on FDA's prior determination that a reasonable assurance of safety and effectiveness exists for the predicate device." *Id.* at 7. The analysis is predominantly relative, and the FDA does not engage in an independent investigation of the medical device's safety and effectiveness. *Id.* ("FDA generally evaluates differences between the new device and the predicate device to determine their effect on safety and effectiveness."). The language of the Guidance Document therefore confirms this court's conclusion that compliance with 510(k) has little to no relevance in a matter of state tort law that revolves around the objective safety of a product. Likewise, Cook's appeal to the Safe Medical Device Act of 1990, which was enacted years before the Guidance Document, is unpersuasive.

E. Motion to Exclude Expert Testimony of Improperly Designated Employees

The plaintiff seeks to exclude the expert testimony of the following Cook employees because they were improperly designated under Federal Rule of Civil Procedure 26: (1) Michael C. Hiles, Ph.D.; (2) Umesh Patel, Ph.D.; (3) Jason Hodde, M.S.; (4) Christopher Fecteau, M.S.E., M.P.H.; (5) Chad Johnson, Ph.D.; (6) Neal Fernot, Ph.D.; and (7) Perry W. Guinn. The plaintiff argues that Cook's designation of these corporate experts was invalid because it disclosed only the names of the employees and their job titles. The plaintiff contends these corporate experts should have submitted expert reports, or, at the very least, that Cook was "required to identify the subject matter, opinions, and facts supporting the witnesses' testimony." (Pl.'s Mot. to Exclude Expert Test. of Improperly Designated Employees ("Pl.'s Mot. re: Employees") [Docket 34], at 2–3). I agree with the latter.

Under Rule 26(a)(2), an expert witness is required to provide a written report when he or she is "retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony." Fed. R. Civ. P. 26(a)(2)(B). Cook's corporate witnesses have not been specially retained to testify in this case and none of them regularly give expert testimony as part of their employment duties. (*See* Cook's Mem. of Law in Opp. to Pl.'s Mot. to Exclude Expert Test. of Cook [Docket 42], at 3). Consistent with the plain language of the rule, as well as the court's treatment of similar witnesses throughout the course of these MDLs, I **FIND** that Cook's corporate witnesses are not required to submit expert reports.

However, disclosures for non-retained corporate experts must state (1) the subject matter on which the witness is expected to present evidence; and (2) a summary of the facts and opinions to which the witness is expected to testify. Fed. R. Civ. P. 26(a)(2)(C). Cook included

neither of these in the designation for its corporate experts, giving the plaintiff no indication as to what these witnesses intend to testify about at trial.

Under Rule 37(c), "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). This court has broad discretion in deciding whether a Rule 26(a) violation is substantially justified or harmless. *Michelone v. Desmarais*, 25 Fed. App'x 155, 158 (4th Cir. 2002). While the majority of Cook's response argues why it was not required to submit expert reports, Cook offers no justification, substantial or otherwise, for its failure to provide any information on the subject matter of these employees' testimony. Accordingly, the question, then, is whether Cook's failure is harmless in that it does not prejudice the plaintiff.

Cook points out that the plaintiff has already taken the depositions of four of the seven corporate experts. Therefore, at this stage in the litigation, the plaintiff has been made aware of the subject matter of those four employees' testimony, weighing against the possibility of prejudice. However, the plaintiff still has practically no information on the three remaining corporate witnesses. Employing my broad discretion, I **DENY** the plaintiff's motion with regard to improperly designated employees and **ORDER** Cook to provide updated disclosures for its corporate experts within **seven days** that state (1) the subject matter on which the witness is expected to present evidence; and (2) a summary of the facts and opinions to which the witness is expected to testify. Fed. R. Civ. P. 26(2)(C).

F. Motion to Exclude the General Liability/Causation Testimony of Robert L. Long, M.D.

Dr. Robert Long, a practicing urologist with thirty-seven years of experience treating female incontinence, offers the general causation opinion that in the patients he has implanted with Cook SIS slings, the product "did not cause them to suffer chronic pelvic or vaginal pain or chronic dyspareunia following the surgeries." (Long Aff. [Docket 53], at 2). In support of this opinion, Dr. Long refers to his twelve years of experience using Cook xenographic slings, his "preferred sling material because of the ease of use, patient tolerance, adaptability of the sling material, and lack of complications." (Long Report [Docket 35-1], at 1). He states that "[t]o date, [he has] not experienced any patients with erosion, extrusion, persistent pelvic pain secondary to the sling placement, dyspareunia secondary to the sling placement, or recurrent urinary tract infection." (*Id.* at 1–2).[19] The plaintiff moves to exclude Dr. Long's opinion on the basis that his expert disclosures do not comply with the requirements of Federal Rule of Civil Procedure 26, nor do they demonstrate reliability as required by *Daubert*. I address these objections in turn.

1. Federal Rule of Civil Procedure 26

In relevant part, Rule 26 provides as follows:

> *Witnesses Who Must Provide a Written Report.* Unless otherwise stipulated or ordered by the court, this disclosure must be accompanied by a written report—prepared and signed by the witness—if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony. The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years; and (v) a statement of the compensation to be paid for the study and testimony in the case.

[19] Dr. Long also offers a specific causation opinion with respect to Ms. Watkins, but challenges to this opinion are not before the court at this time.

Fed. R. Civ. P. 26(a)(2)(B). If a report is incomplete or incorrect in some material respect, the party must supplement its report with the additional or corrective information. Fed. R. Civ. P. 26(e). Any supplemental information must be disclosed at least thirty days before trial. *Id.* (requiring additions or changes to expert disclosures to be disclosed "by the time the party's pretrial disclosures under Rule 26(a)(3) are due"). Here, in addition to an expert report regarding Ms. Watkins, (*see* Long Report [Docket 35-1]), on February 23, 2015, Dr. Long provided a supplemental sworn affidavit regarding his opinions, (*see* Long Aff. [Docket 53]). Trial is scheduled for May 18, 2015. Therefore, the supplemental affidavit is timely, and I consider it along with the initial expert report in determining the adequacy of the expert disclosure.[20]

The plaintiff argues that Dr. Long's expert disclosure falls short of the Rule 26 requirements in that it "offers no supporting authority." (Pl.'s Mot. to Exclude General Liability/Causation Test. of Robert L. Long, M.D. ("Pl.'s Mot. re: Long") [Docket 35], at 4). Although Dr. Long's expert disclosure is cursory, I find that it adequately states his opinion and the authority supporting it for the purposes of Rule 26. He explains that his opinion was informed by his observations of and experience with SIS patients over the past twelve years, as well as his review of Ms. Watkins's medical records. (Long Report [Docket 35-1], at 1–2). Dr. Long also provided his *curriculum vitae*, which includes his educational background, medical experience, fellowships, memberships, and publications. (Cook's Ex. 3 [Docket 44-3]). Finally, he provided a list of supporting scientific literature. (Long Aff. [Docket 53], 2–3). This is enough to satisfy Rule 26, a discovery requirement simply meant to ensure that the opposing party has a "reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from other witnesses." Fed. R. Civ. P. 26 advisory committee notes; *see also*

[20] I refer to Dr. Long's initial expert report [Dockets 35-1] and his supplemental affidavit [Docket 53] collectively as his "expert disclosure."

Ciomber v. Coop. Plus, Inc., 527 F.3d 635, 642 (7th Cir. 2008) ("The purpose of Rule 26(a)(2) is to provide notice to opposing counsel [] as to what the expert witness will testify . . . ."). But whether or not the supporting authority cited by Dr. Long in his expert disclosure is enough to satisfy the reliability requirements of Federal Rule of Evidence 702—that it is relevant, scientifically valid, and supportive of the expert's opinions—is another matter. Thus, finding no Rule 26 error in Dr. Long's expert disclosure, I now apply *Daubert*'s analysis to his opinions.

2. Reliability of Methodology

The plaintiff contends that the court should exclude Dr. Long's opinions because they are conclusory statements with no identifiable supporting authority or scientific methodology. Consequently, in the plaintiff's view, Dr. Long's expert disclosure is comprised of improper *ipse dixit*, or "opinions justified solely by the fact that a qualified expert holds them." (Pl.'s Mot. re: Long [Docket 35], at 4). The limited information set forth in Dr. Long's expert disclosure, though sufficient to get by the plaintiff's Rule 26 challenge, is not complete enough to make a reliability decision under *Daubert* at this time.

Dr. Long primarily refers to his experience as a urologist in reaching his opinion. He states that during the last twelve years of his practice, Cook SIS slings "have been [his] preferred sling material," (Long Report [Docket 35-1], at 1), and that in his experience, Cook SIS slings do not cause patients to suffer injury following the surgery, (Long Aff. [Docket 53], at 2). While experience can be "the predominant, if not sole, basis for a great deal of reliable expert testimony," the court must ensure that the expert can "explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee notes. Generally, under this analysis, a doctor who has extensive experience with a medical device may

offer opinions on the use of that device. But when the opinion crosses into causation, like Dr. Long's, an unscientific sample of the expert's patients is not an adequate foundation to suggest reliability under *Daubert*, and the court needs further explanation from the expert on how his experience leads to a causation opinion in order to make a reliability determination.

Dr. Atala, for instance, provided the needed explanation by referring to and elaborating on his co-authored peer-reviewed study, which mirrored his observations as a pelvic surgeon and established a reliable basis for his opinion on medical causation. Only equipped with Dr. Long's abbreviated Rule 26 expert disclosure, the court cannot tell if Dr. Long has a similar basis for his causation opinions. Dr. Long lists ten articles that "are consistent with" his opinion, (Long Aff. [Docket 53], at 3–4), but unlike Dr. Atala, he does not convey how he relied on these articles in reaching his opinion. Indeed, beyond listing them in his affidavit, he does not mention these articles in his expert disclosure at all. It is possible that he thoroughly read the authors' work and used their results to come to his opinion in this case. But the court has no way to make an informed conclusion. Put simply, without a more developed record, such as sworn testimony via deposition or interrogatories, the court cannot make an informed decision about the reliability of Dr. Long's general causation opinions.[21]

Therefore, the court **RESERVES** judgment on the plaintiff's motion with respect to Dr. Long [Docket 35]. A short hearing (outside the presence of the jury) will be held on this matter at a convenient time during trial.

[21] In a footnote, the plaintiff also challenges the relevance of Dr. Long's opinion that the product's side-effect of recurring incontinence occurs at the rate disclosed by the literature and that the SIS product is better than other mesh products. (*See* Mot. re: Long [Docket 35], at 6 n.3). I find that because the plaintiff claims recurrence as one of her injuries, testimony regarding the rate of that side-effect is relevant. I further find that a comparison of Cook's product to other mesh products might be relevant to the risk-utility analysis applied to design-defect claims under Georgia law. *See Banks v. ICI Ams., Inc.* 450 S.E.2d 671, 674–75 (Ga. 1994) (adopting the risk-utility test for design-defect claims, which includes a consideration of alternative safer designs). Thus, I decline to exclude these opinions on the basis of relevance at this time.

V. Effect of *Daubert* Ruling

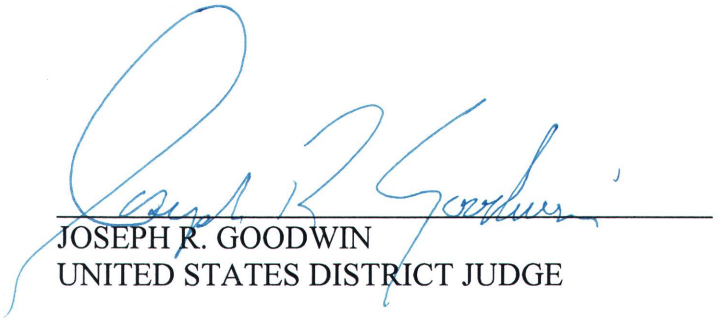
I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VI. Conclusion

To reiterate: Defendants' Motion to Exclude the Opinions and Testimony of Donald Kreutzer, Ph.D. [Docket 36] is **DENIED**; defendants' Motion to Exclude the Opinions and Testimony of Lisa Morici, Ph.D. [Docket 38] is **GRANTED in part** and **DENIED in part**; defendants' Motion to Exclude the Opinions and Testimony of Daniel S. Elliott, M.D. [Docket 40] is **DENIED**; plaintiff's Motion to Exclude General Liability/Causation Testimony of Anthony Atala, M.D. [Docket 30] is **DENIED**; plaintiff's Motion to Exclude General Liability/Causation Testimony of Dennis Metzger, Ph.D. [Docket 32] is **DENIED**; plaintiff's Motion to Exclude the Testimony of Dr. Stephen Park Rhodes [Docket 33] is **GRANTED**; and plaintiff's Motion to Exclude Expert Testimony of Improperly Designated Employees [Docket 34] is **DENIED**. It is further **ORDERED** that Cook provide the plaintiff with expert compensation information for Dr. Atala and updated disclosures for its corporate experts within **seven days** of the entry of this Memorandum Opinion and Order. Finally, the court **RESERVES** judgment on plaintiff's Motion to Exclude General Liability/Causation Testimony of Mickey Karram, M.D. [Docket 31] and plaintiff's Motion to Exclude General Liability/Causation Testimony of Robert L. Long, M.D. [Docket 35].

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: March 25, 2015



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE